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CERTIFICATE OF MAILING

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Curtis L. Schrandt

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vitolone et al.
U.S. Application No.	: 10/031,423
U.S. Application Filed	: 01/16/02
International Application No.	: PCT/IB00/00966
International Filing Date	: 14 July 2000 (14.07.00)
Title of Invention	: PROCESS FOR THE QUANTITATIVE DETERMINATION OF ALKALOIDS SUCH AS COCAINE IN A SOLID SAMPLE AND REAGENT FOR USE IN SUCH PROCESS
Examiner	: L. A. Alexander
Art Unit	: 1743

Commissioner for Patents
P.O. 1450
Alexandria, VA 22313-1450

MEMORANDUM

S I R:

This memorandum is in reference to the Office Action mailed July 19, 2004 in the above-identified application. This memorandum is not an amendment and is not to be entered in the application. This memorandum is for the Examiner's eyes only.

The Examiner points out in the Office action that the Office inadvertently did not consider the Preliminary Amendment filed on January 16, 2002 with the original application. However, it appears that the Office also did not consider the substitute claims that were submitted at the same time. The substitute claims (which were attached to and made a part of

the substitute specification) comprised Article 34 amendments made in the international application, i.e., PCT/IB00/00966.

The present Office Action appears to be applying the claims in the Preliminary Amendment to the original claims as published in the international application, rather than the substitute claims comprising the Article 34 amendments that should have been entered in the application at the initial filing.

Enclosed herewith is a marked up version of the current state of the claims showing the amendments on the Preliminary Amendment as incorporated into the substitute claims that we filed with the original application. Also enclosed in a clean copy of the claims as they stand at this time.

Should the Examiner believe that direct contact with applicant's attorney would clear up the apparent confusion relating to the current state of the claims in the application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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By: _____

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Dated: August 12, 2004

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cc: Examiner L. A. Alexander @ 703-872-9306 (15 pp.)

Not an amendment
Do not enter.

SUBSTITUTE CLAIMS (ARTICLE 34 AMENDED CLAIMS) FILED WITH APPLICATION, AS FURTHER AMENDED BY PRELIMINARY AMENDMENT DATED JANUARY 16, 2002 (ALSO FILED WITH APPLICATION)

CURRENT STATE OF CLAIMS IN THE APPLICATION PRIOR TO ANY OFFICE ACTION (NON-MARKED UP VERSION)

1. A screening-type process for the quantitative determination of cocaine and other alkaloids which are present in a solid sample which includes the steps of:

a) preparing a solid sample in a finely divided or powdered form;

b) selecting a liquid reagent providing constant concentration of hydroxyl groups suitable for extracting and transforming cocaine into benzoylecgonine and for extracting other similar substances;

c) extracting cocaine and other similar substances contained in the sample and transforming the extracted cocaine into benzoylecgonine by maintaining the sample completely immersed in said liquid reagent at a temperature ranging from 10°C to 250°C for a period of time ranging from few seconds to 48 hours; and

d) analysing the liquid separated from the solid sample to determine the concentration of benzoylecgonine contained in said liquid with respect to the cut-off limit using a conventional screening kit for the determination of the said substance in urine.

2. Process according to claim 1, wherein said solid sample is a sample of hair.

3. Process according to claim 1, wherein said temperature is ranging from 100°C to 150°C.

4. Process according to claim 1, wherein said period of time is ranging from 15 minutes to 24

hours.

5. Process according to claim 1, wherein said temperature is maintained at 100°C for 1 hour.

6. Process according to claim 1, wherein said liquid reagent is an ammonia buffer comprising 0.2 M (NH4)2HPO4 with the addition of 5 ml of 25% NH4OH to each liter thereof.

7. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of from 0.0001M to 5 M.

8. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.03M to 0.5 M.

9. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.04M to 0.33 M.

10. Process according to claim 1, wherein the analyzed samples are arranged in increasing order of concentration of cocaine or other alkaloids.

11. Process according to claim 1, wherein the samples are subjected to confirmation analyses with standard techniques such as GC or GC/MS.

12. Process according to claim 2, wherein each hair sample is made of about 50mg to 300 mg of

finely divided and/or powdered hair.

13. Process according to claim 1, wherein said liquid reagent is a solution comprising a solute selected among aluminum hydroxide, barium hydroxide octahydrate, benzyltriethylammonium hydroxide, benzyltrimethylammonium hydroxide, calcium hydroxide, phenylhydrargirium hydroxide, lithium hydroxide, lithium hydroxide monohydrate, magnesium hydroxide, potassium hydroxide, potassium hydroxyantimoniate, sodium hydroxide, sodium hydroxide monohydrate, strontium hydroxide octahydrate, tetramethylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, dissolved in a solvent selected among ethanol, methanol, water, monobasic ammonium phosphate, ammonium acetate, ammonium benzoate, ammonium bicarbonate, ammonium bichromate, ammonium bisulphate, ammonium bromide, ammonium carbamate, ammonium carbonate, ammonium citrate bibasic, ammonium chromate, ammonium iodide, molibdate, ammonium monovanadate, ammonium nitrate, ammonium oxalate monohydrate, ammonium persulphate, ammonium sulphate, ammonium sulphamate, ammonium sulphite, ammonium sulphide, ammonium tartrate, ammonium thiocyanate, ammonium thioglycolate, ammonium thiosulphate, ammonium chloride, sodium phosphate monobasic, sodium phosphate bibasic, potassium phosphate monobasic, potassium phosphate bibasic.

14. Diagnostic kit for carrying out the process according to claim 1, comprising a liquid reagent with constant concentration of hydroxyl groups suitable for extracting cocaine and other alkaloids and transforming cocaine into benzoylecgonine, and a conventional screening kit for the determination of said metabolite in urine samples.

not an Amendment
Do Not Enter.

SUBSTITUTE CLAIMS (ARTICLE 34 AMENDED CLAIMS) FILED WITH APPLICATION, AS FURTHER AMENDED BY PRELIMINARY AMENDMENT DATED JANUARY 16, 2002 (ALSO FILED WITH APPLICATION)

CURRENT STATE OF CLAIMS IN THE APPLICATION PRIOR TO ANY OFFICE ACTION (MARKED UP VERSION)

1. A screening-type process for the quantitative determination of cocaine and other alkaloids which are present in a solid sample which includes the steps of:

a) preparing a solid sample in a finely divided or powdered form;

b) selecting a liquid reagent providing constant concentration of hydroxyl groups suitable for extracting and transforming cocaine into benzoylecgonine and for extracting other similar substances;

c) extracting cocaine and other similar substances contained in the sample and transforming the extracted cocaine into benzoylecgonine by maintaining the sample completely immersed in said liquid reagent at a temperature ranging from 10°C to 250°C for a period of time ranging from few seconds to 48 hours; and

d) analysing the liquid separated from the solid sample to determine the concentration of benzoylecgonine contained in said liquid with respect to the cut-off limit using a conventional screening kit for the determination of the said substance in urine.

2. Process according to ~~claims~~ claim 1, wherein said solid sample is a sample of hair.

3. Process according to ~~claims~~ claim 1 ~~and 2~~, wherein said temperature is ranging from 100°C to 150°C.

4. Process according to ~~claims~~ claim 1 ~~and 2~~, wherein said period of time is ranging from 15 minutes to 24 hours.

5. Process according to ~~any preceding claims~~ claim 1, wherein said temperature is maintained at 100°C for 1 hour.

6. Process according to claim 1, wherein said liquid reagent is an ammonia buffer comprising 0.2 M (NH4)2HPO4 with the addition of 5 ml of 25% NH4OH to each liter thereof.

7. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of from 0.0001M to 5 M.

8. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.03M to 0.5 M.

9. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.04M to 0.33 M.

10. Process according to ~~any preceding claims~~ claim 1, wherein the analyzed samples are arranged in increasing order of concentration of cocaine or other alkaloids.

11. Process according to ~~claim any preceding claims~~ claim 1, wherein the samples are subjected to confirmation analyses with standard techniques such as GC or GC/MS.

12. Process according to ~~any preceding claims~~ claim 2, wherein each hair sample is made of about 50mg to 300 mg of finely divided and/or powdered hair.

13. Process according to claim 1, wherein said liquid reagent is a solution comprising a solute selected among aluminum hydroxide, barium hydroxide octahydrate, benzyltriethylammonium hydroxide, benzyltrimethylammonium hydroxide, calcium hydroxide, phenylhydrargirium hydroxide, lithium hydroxide, lithium hydroxide monohydrate, magnesium hydroxide, potassium hydroxide, potassium hydroxyantimoniate, sodium hydroxide, sodium hydroxide monohydrate, strontium hydroxide octahydrate, tetramethylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, dissolved in a solvent selected among ethanol, methanol, water, monobasic ammonium phosphate, ammonium acetate, ammonium benzoate, ammonium bicarbonate, ammonium bichromate, ammonium bisulphate, ammonium bromide, ammonium carbamate, ammonium carbonate, ammonium citrate bibasic, ammonium chromate, ammonium iodide, molibdate, ammonium monovanadate, ammonium nitrate, ammonium oxalate monohydrate, ammonium persulphate, ammonium sulphate, ammonium sulphamate, ammonium sulphite, ammonium sulphide, ammonium tartrate, ammonium thiocyanate, ammonium thioglycolate, ammonium thiosulphate, ammonium chloride, sodium phosphate monobasic, sodium phosphate bibasic, potassium phosphate monobasic, potassium phosphate bibasic.

14. Diagnostic kit for ~~the~~ carrying out ~~of~~ the process according to ~~any claims 1 to 13~~ claim 1, comprising a liquid reagent with constant concentration of hydroxyl groups suitable for

extracting cocaine and other alkaloids and transforming cocaine into benzoylecgonine, and a conventional screening kit for the determination of said metabolite in urine samples.